Notice of Participation
Docket No. N-0297

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Brief Summary following pages

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"FDA PDMA Hearing" 7 '00 OCT 17 P1:27

Statement from Blood Centers of America, Inc.
for the Public Hearing On Prescription Marketing Act
October 27, 2000 Rockville MD

Presented by
Laura McDonald, Program Manager, BCA/hemerica

This statement represents Blood Centers of America, its subsidiary, hemerica, inc. and the 30 blood collection organizations in the United States we represent. These organizations produce 525,000 liters of recovered plasma annually from which almost twenty million grams of therapeutic proteins are derived. Many of these blood collection organizations distribute the blood derivatives manufactured from this plasma.

The purpose of this statement is to make certain points about the above Act as they relate directly to the services provided by community blood centers and the deleterious impact this Act would have on both the provision of these services and the health care entities served. We believe there is a simple logic to these points which the Agency should seriously consider.

1. The act was enacted to protect the public against the threat of subpotent, adulterated, counterfeit and misbranded drugs by the existence of drug diversion schemes and drug diversion sub-markets. It proposes to accomplish this by prohibiting commerce of any prescription drug that "was purchased by a public or private hospital or other health care entity." Wholesaler distributors of drugs and retail pharmacies licensed under state law are exempt from PDMA. Health care entity is defined as any person that provides diagnostic, medical, surgical, or dental treatment, or chronic and rehabilitative care.

2. The obvious intent of the act is to avoid the creation and operation of a secondary markets or "black markets" for blood derivatives.

3. Blood centers are unique under the definitions in the Act because their primary business may be considered to be that of a manufacturer and wholesaler. The blood and blood components which are the primary products distributed by blood centers are expressly exempt from PDMA. These are sold to hospitals which fulfill a retail role in making these products available to patients. Blood centers fall under the edge of PDMA's definition of health care entity to the extent some centers provide minimal services directly to patients which may include certain diagnostic of therapeutic services. However, the vast majority of blood center commerce may be considered to be "wholesale" in nature.

4. Blood centers are also unique under the definitions in the Act because they make the raw materials from which blood derivatives are produced available to manufacturers. A number of these blood centers have traditionally distributed these blood derivatives for years. These blood derivatives are a logical extension of the menu of blood products derived from whole blood.

5. Where there is distribution of blood derivatives by blood centers, an important public service is provided. In times of shortage or product mix imbalances, blood centers engaged in blood derivative distribution have been able to assure a consistent supply of blood derivatives to communities which made the starting material, recovered plasma, available. This is an effective and fair method of rationing which PDMA would eliminate.

6. The fact that blood centers have engaged in the wholesale distribution of blood derivatives and should be permitted to continue is consistent with the intent of PDMA. Blood centers have always acquired these products for the primary purpose of distribution among the hospitals they serve. There is no intent to divert blood derivatives for any of the reasons PDMA is intended to protect the public from.

7. To suggest by the exclusion of blood centers from the distribution of blood derivatives through PDMA that the intent of blood centers has been to engage in a secondary market defames the role which blood centers have served and has the potential to dislocate hospitals from a reliable supply of blood derivatives in periods of product shortage.

The above points are intended to show the Agency that the business purposes of blood centers engaged in the distribution of blood derivatives are consistent with the intent of PDMA and that blood centers should be specifically exempt from the definition of healthcare entity in PDMA.